ABSTRACT

VALIDATION OF STABILITY-INDICATING HPLC METHOD FOR KETOCONAZOLE IN PHARMACEUTICAL TABLETS

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The objective of the present study was to obtain HPLC analysis method that could separate ketoconazole from the degradation product in pharmaceutical tablets. The method development was started from forced degradation studies including acidic, basic, oxidative, thermal and photolytic degradations in the ketoconazole sample. The separation was achieved by LiChrospher® C_{18} Column (250 x 4.6 mm i.d., 5µm) using mobile phase consisting of 0.4% diisopropylamine in methanol : acetic buffer pH 6.5 (80:20 v/v) at flow rate of 1 mL/min and detection at 263 nm. The injection volume was 20 µL and the column temperature was 25^0C. The retention time of ketoconazole was found to be 5.501 min. The method showed linearity with correlation coefficient 0.9998 and regression equation y = 9.8235x-156.54 over the range of 200-600 µg/mL. The mean recovery was found to be 100.42% with relative standard deviation of 0.89%. The method was validated in terms of selectivity, linearity, accuracy, precision and robustness. As the proposed method could effectively separate the drug from its degradation products, it can be employed as a stability-indicating method for the determination of instability of Ketoconazole in pharmaceutical tablets

Keywords : Ketoconazole, Stability-indicating method, HPLC, Validation